WO 2004/096332

CLAIMS

A mask system for treating sleep disordered breathing comprising headgear, a shell/cushion including a
channel adjacent a front aperture, a frame, an elbow including at least one undercut on a proximal end and a
retaining ring including a rear flange adapted to be retainably insertable in the channel of the shell/cushion
and a front flange adapted to retainably engage with the at least one undercut of the elbow.

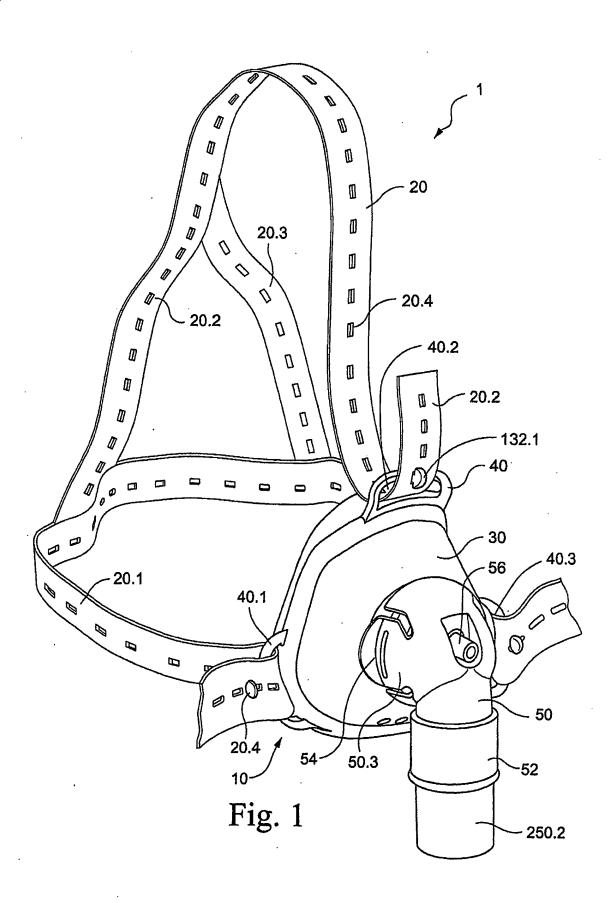
21

- 2. A mask system as claimed in claim 1 further comprising a thin walled section adjacent the channel of the shell/cushion which is adapted to tear upon removal of the elbow.
- 3. A mask system for treating sleep disordered breathing comprising headgear, a frame, and shell/cushion including a frame-receiving channel defined by a front flange and a rear flange, the front flange extending 75% to 100% of the way around the perimeter of the shell/cushion, wherein the frame is adapted to be removably insertable in the frame-receiving channel of the shell/cushion.
- 4. A mask system as claimed in claim 3 wherein in at least a nasal bridge region of the shell/cushion adapted to contact the nasal bridge region of a patient the rear flange is from 1mm to 3mm thick.
- 5. A mask system as claimed in claim 4 wherein the rear flange is approximately 2mm thick.
- 6. A connection piece for connecting a mask to a conduit which can carry an air flow to said mask, said connection piece including an inlet and an outlet and a passage wall to carry said air flow therebetween, the connection piece including, in the vicinity of said outlet between said outlet and said inlet, a vent wall extending away from said passage wall, said vent wall including at least one aperture therethrough.
- 7. A connection piece as claimed in claim 6, wherein said connection piece is formed integrally with said mask.
- 8. A connection piece as claimed in claim 6, wherein said piece is formed separately of said mask and can be joined or attached thereto.
- A connection piece as claimed in any one of claims 6 to 8, wherein said piece is formed integrally with said conduit.
- 10. A connection piece as claimed in any one of claims 6 to 8, wherein said piece is formed separate from said conduit and can be joined or attached thereto.
- 11. A connection piece as claimed in any one of claims 6 to 10, wherein said connection piece is formed so that the outlet lies at any appropriate angle to said inlet.
- 12. A connection piece as claimed in claim 11, wherein said connection piece is formed so that said outlet lies at an angle to said inlet which angle is in the range of 90° to 180°.
- 13. A connection piece as claimed in claim 12, wherein said connection piece is a 90° elbow.
- 14. A connection piece as claimed in any one of claims 6 to 13, wherein said piece includes attachment structure to attach said connection piece to said mask.
- 15. A connection piece as claimed in claim 14, wherein said attachment structure includes at least one snap-in undercut to engage a mating flange on said mask.
- 16. A connection piece as claimed in claim 14 or 15, wherein said attachment structure releasably attaches said connection piece to said mask.
- 17. A connection piece as claimed in claim 16, wherein said attachment structure includes moveable portions on which said snap-in undercuts are formed, said moveable portions allowing said undercuts to disengage said flange.

- 18. 'A connection piece as claimed in any one of claims14 to 17, wherein said attachment structure allows rotation of said connection piece relative to said mask.
- 19. A connection piece as claimed in any one of claims 6 to 13, wherein said piece includes attachment means to attach said connection piece to said mask.
- 20. A connection piece as claimed in claim 19, wherein said attachment means includes at least one snap-in undercut to engage a mating flange on said mask.
- 21. A connection piece as claimed in claim 19 or 20, wherein said attachment means releasably attaches said connection piece to said mask.
- 22. A connection piece as claimed in claim 21, wherein said attachment means includes moveable portions on which said snap-in undercuts are formed, said moveable portions allowing said undercuts to disengage said flange.
- 23. A connection piece as claimed in any one of 19 to 22, wherein said attachment means allows rotation of said connection piece relative to said mask.
- 24. A connection piece as claimed in any one of claims 6 to 23, wherein said connection piece includes a Luer port through said passage wall.
- 25. A connection piece as claimed in any one of claims 6 to 24, wherein said vent wall lies at an oblique angle to said air flow.
- 26. A connection piece as claimed in claim 25, wherein said angle is in the range of 25° to 155°.
- 27. A connection piece as claimed in any one of claims 6 to 26, wherein said piece includes on its external surface a recess having wall portions extending away from an external side of said vent wall.
- 28. A connection piece as claimed in claim 27, wherein said wall portions diverge in a direction away from said vent wall.
- 29. A mask for treating sleep disordered breathing, said mask having a shell/cushion with an inner and outer surface, a flange extending away from said outer surface and surrounding said shell/cushion, said mask having an exoskeletal frame having a shape which substantially matches the contours of said flange so that said frame can be positioned adjacent said flange when said shell/cushion is in a shape suitable for use by a patient, and structure to hold said flange to said frame.
- 30. A mask as claimed in claim 29, wherein said structure to hold said flange to said ring member includes one or more apertures through said flange.
- 31. A mask as claimed in claim 29, wherein rivets or other fixers pass through said apertures to hold said flange adjacent said frame.
- 32. A mask as claimed in any one of claims 29 to 31, wherein said frame is optionally structured for attachment to headgear to position said mask onto a patient's head.
- 33. A mask for treating sleep disordered breathing, said mask having a shell/cushion with an inner and outer surface, a flange extending away from said outer surface and surrounding said shell/cushion, said mask having an exoskeletal frame having a shape which substantially matches the contours of said flange so that said frame can be positioned adjacent said flange when said shell/cushion is in a shape suitable for use by a patient, and means to hold said flange to said frame.

- 34. A mask as claimed in claim 33, wherein said means to hold said flange to said ring member includes one or more apertures through said flange.
- 35. A mask as claimed in claim 33, wherein rivets or other fixers pass through said apertures to hold said flange adjacent said frame.
- 36. A mask as claimed in any one of claims 33 to 35, wherein said frame includes means for attachment to headgear to position said mask onto a patient's head.
- 37. A mask as claimed in any one of claims 29 to 36, wherein said frame includes at least one connection member connected to said frame for cooperating therewith to sandwich said flange between said at least one connection member and said frame.
- 38. A mask as claimed in claim 37, wherein said at least one connection member is hinged to said frame.
- 39. A mask as claimed in claim 37, wherein said at least one connection member is connected to said frame by a flexible connection.
- 40. A mask as claimed in any one of claims 29 to 39, wherein a second ring member of a shape which substantially matches the contours of said flange, whereby said flange is sandwiched between said first mentioned ring member and said second ring member.
- 41. A mask as claimed in any one of claims 29 to 40, wherein said second ring member, said flange and said first mentioned ring member are held together via rivets and/or fixers.
- 42. A mask as claimed in claim 41, wherein said second ring member includes rivets extending therefrom, which can pass through said flange and said first mentioned ring member.
- 43. A mask as claimed in claim 41, wherein said first mentioned ring member includes rivets extending therefrom, which can pass through said flange and said second ring member.
- 44. A mask as claimed in claim 41, wherein said flange includes a first set of rivets extending in a forward direction and a second set of rivets extending in a rearward direction, said first set of rivets being received in apertures through said first mentioned ring member, said second set of rivets being received in apertures through said second ring member,
- 45. A mask as claimed in any one of claims 42 to 44, wherein said rivets are deformable at their free end.
- 46. A mask as claimed in any one of claims 42 to 44, wherein said rivets include a deformable undercut so that the undercut can pass through said apertures to then resume their shape to hold components together.
- 47. A mask system including head gear and mask as claimed in any one of claims 29 to 46.
- 48. A mask system as claimed in claim 47, wherein said mask system includes a connection piece as claimed in anyone of claims 6 to 28.
- 49. A mask system including headgear, a mask and a connection piece as claimed in any one of claims 6 to 28.
- 50. A mask system as claimed in claim 1 or 2, wherein said elbow includes structure to prevent said aperture separating from said retaining ring during normal use.
- 51. A mask system as claimed in claim 1 or 2, wherein said elbow provides means to prevent said aperture separating from said retaining ring during normal use.
- 52. A mask system as claimed in any one of the preceding claims wherein said elbow or said connection piece when separate form said mask has a cylindrical outlet.

53. A mask system as claimed in claim 52, wherein said shell/cushion includes an annular flange which when assembled with said elbow or said connection piece engages a rim of said outlet to thereby suitably seal said outlet to said flange.



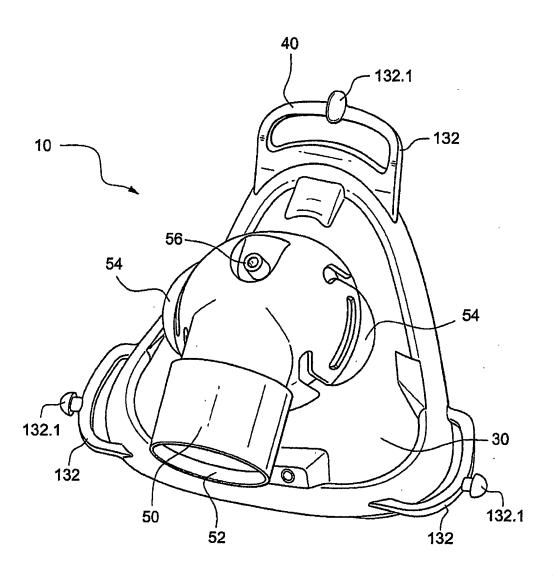


Fig. 2

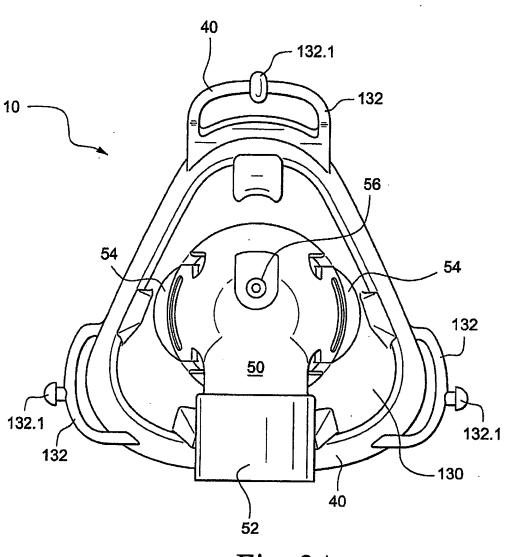
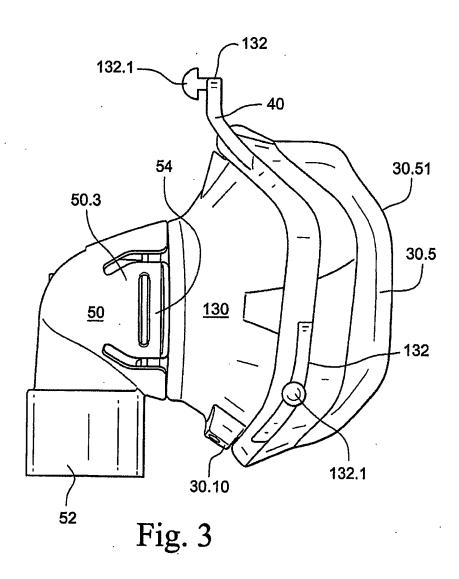
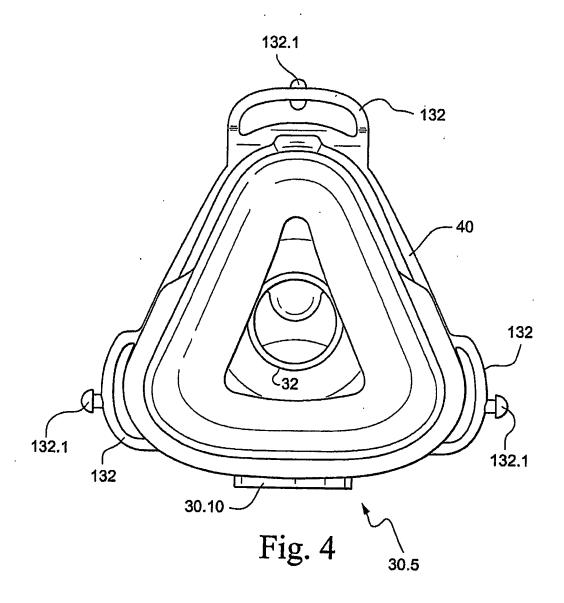
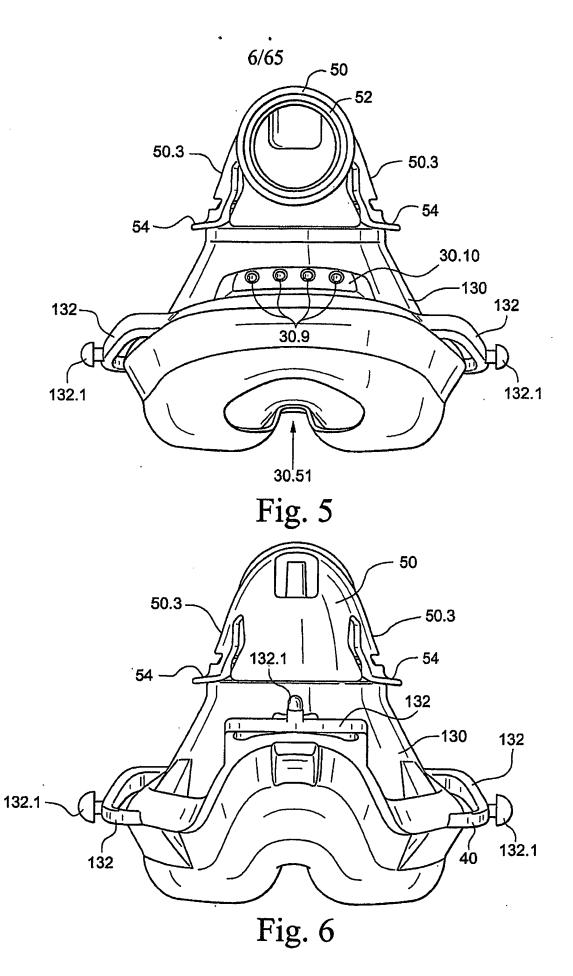


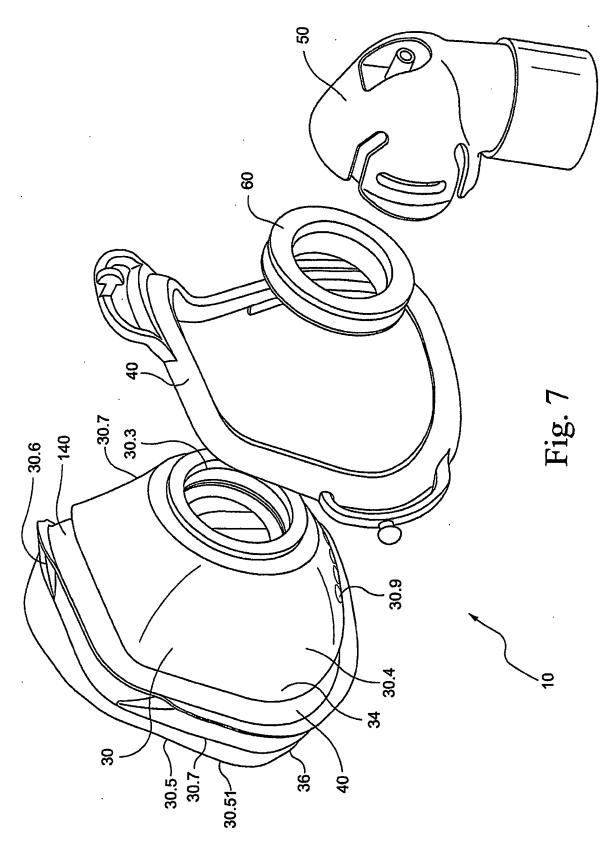
Fig. 2A

4/65









SUBSTITUTE SHEET (RULE 26)

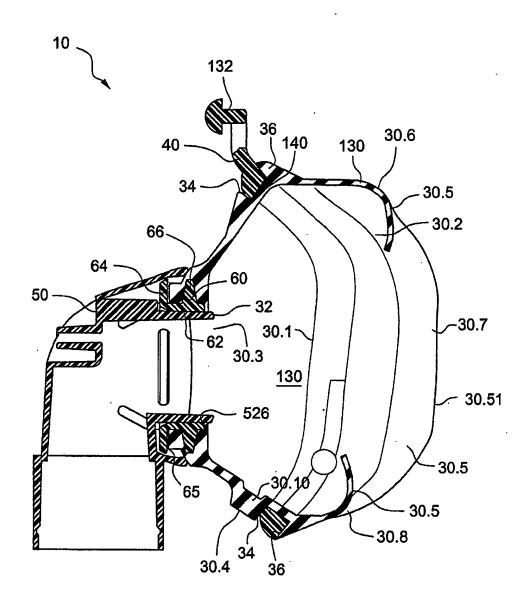


Fig. 8

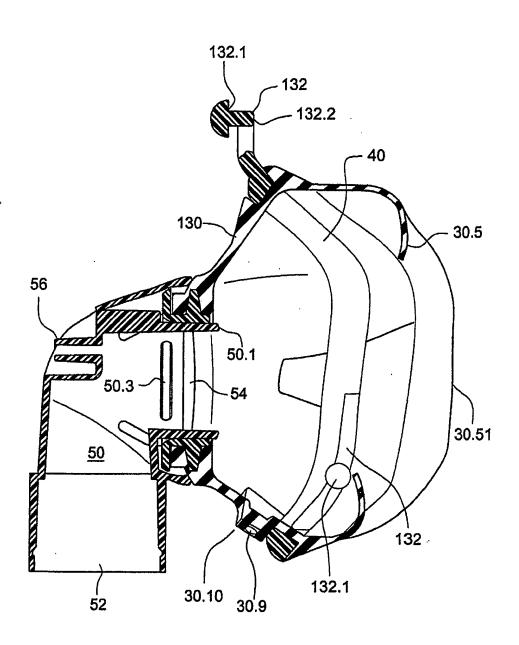


Fig. 9

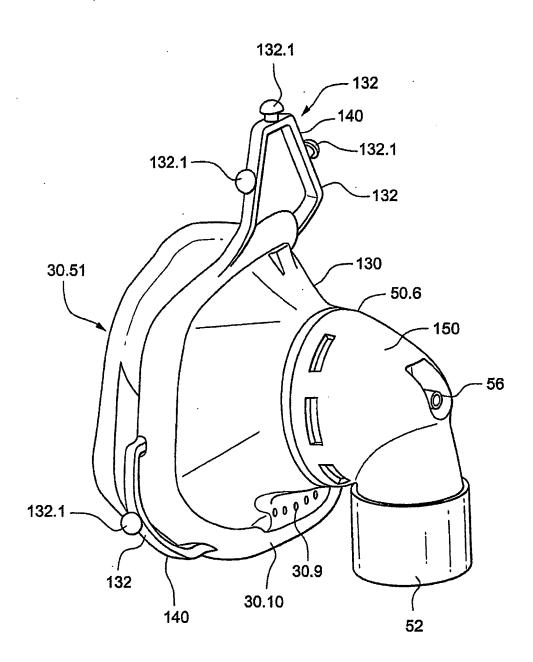
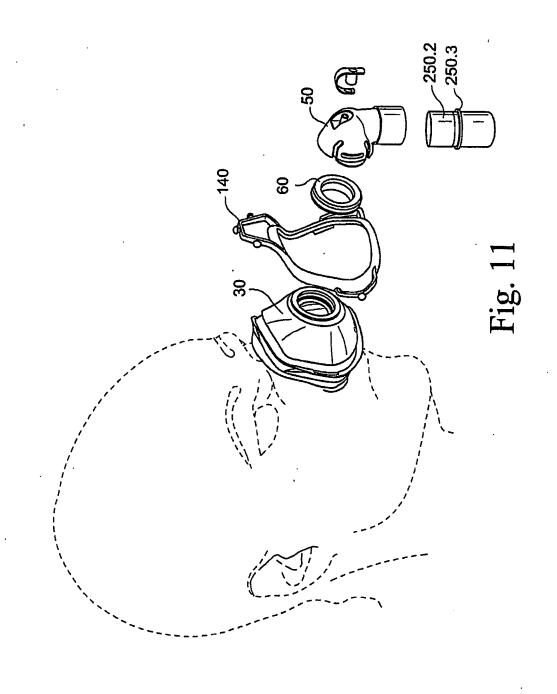
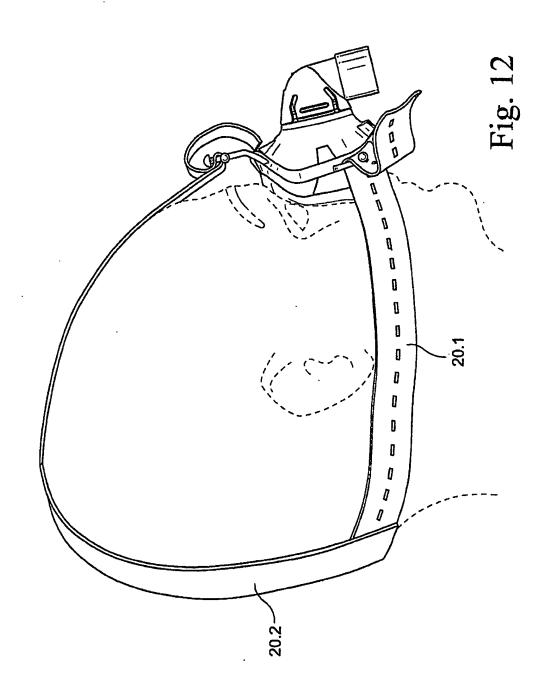
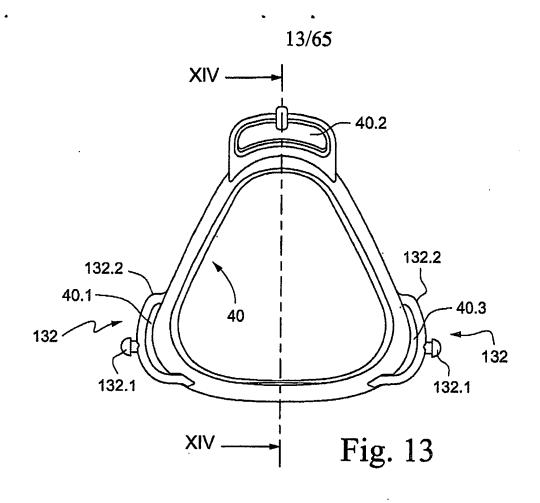


Fig. 10







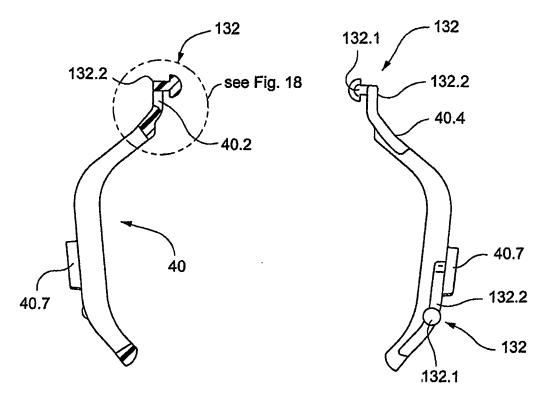


Fig. 14

Fig. 15

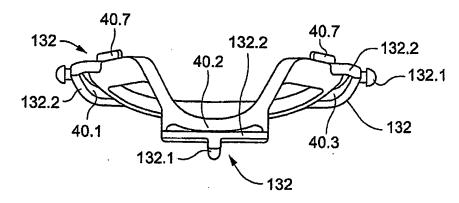


Fig. 16

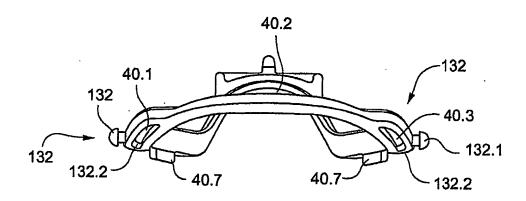
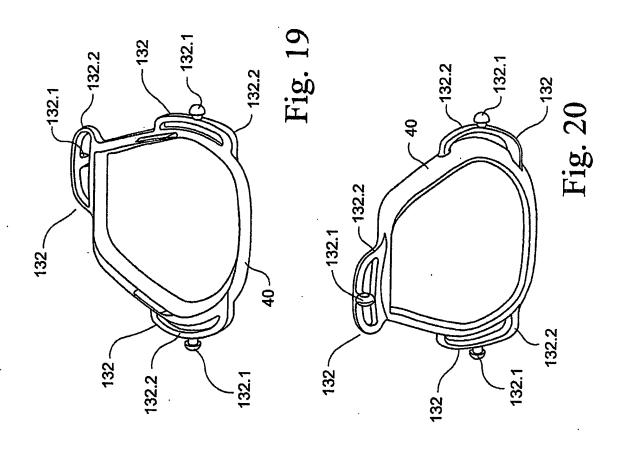
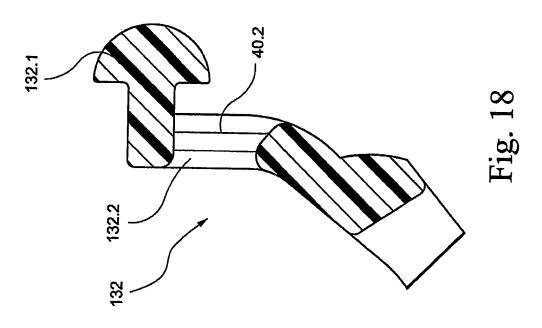
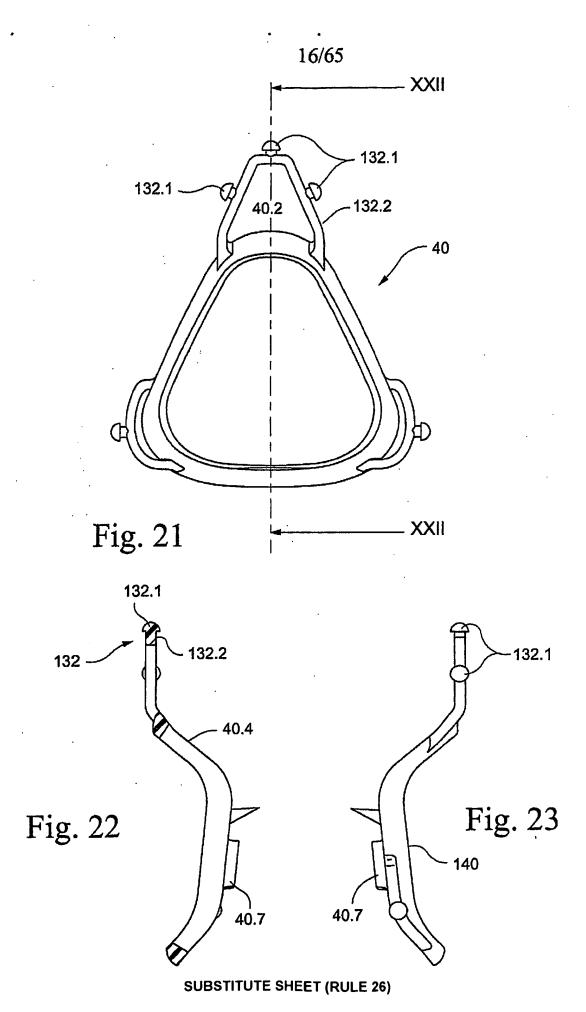


Fig. 17





SUBSTITUTE SHEET (RULE 26)



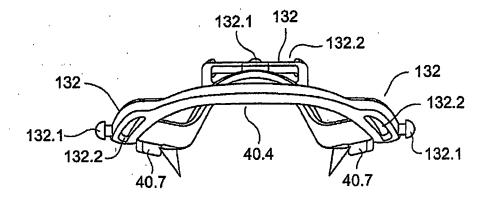
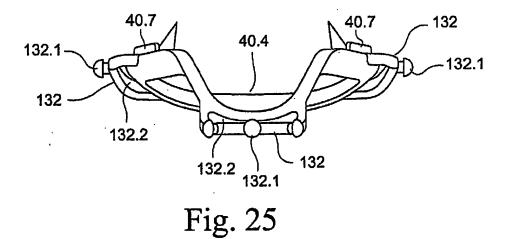
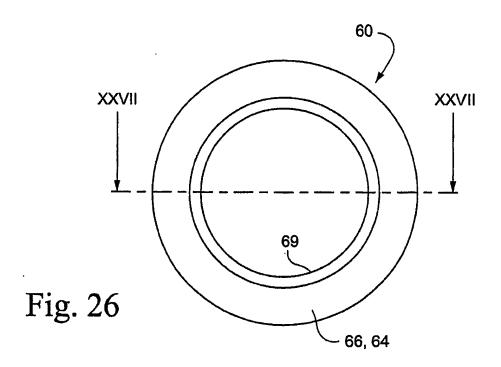


Fig. 24





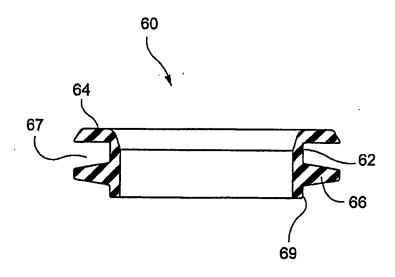
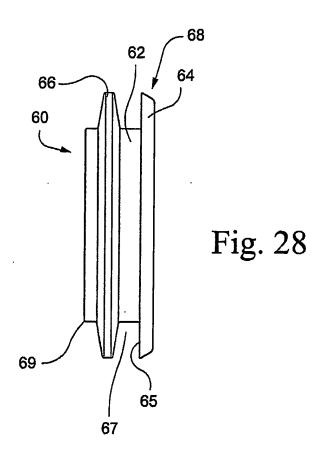


Fig. 27





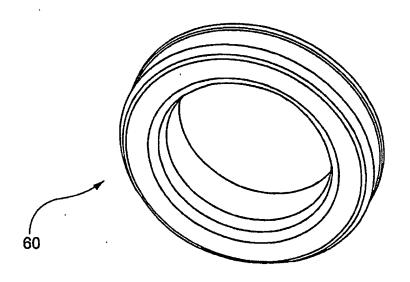
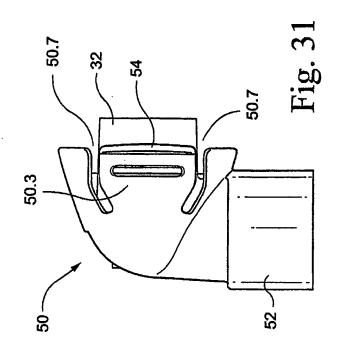
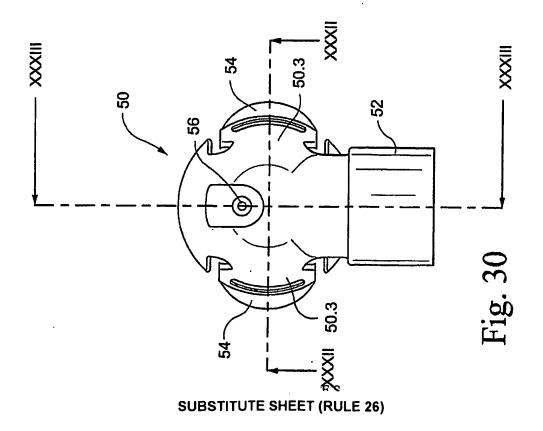
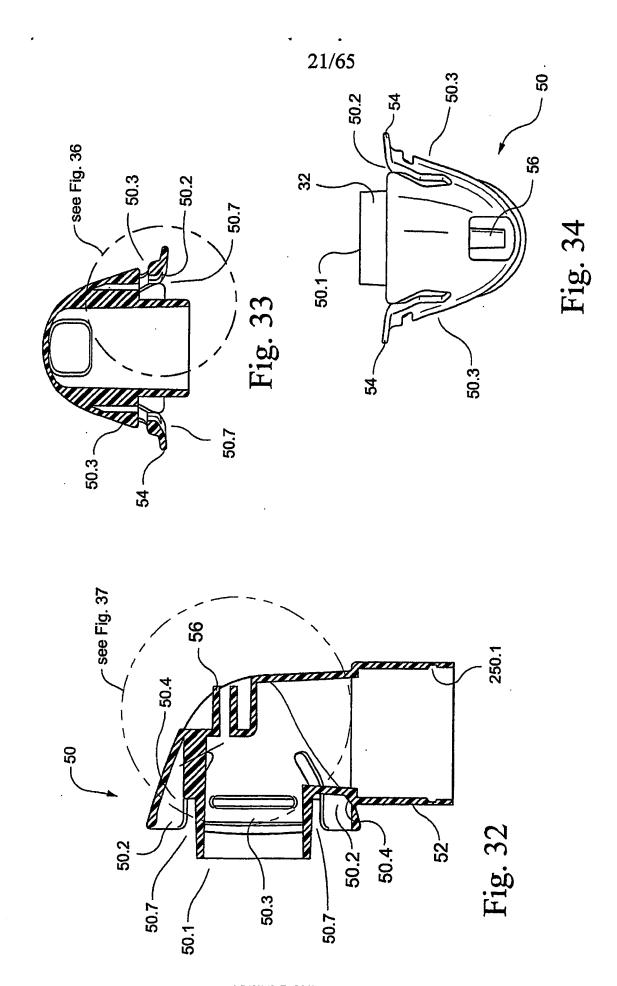


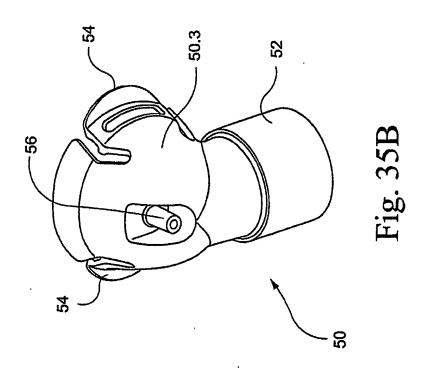
Fig. 29

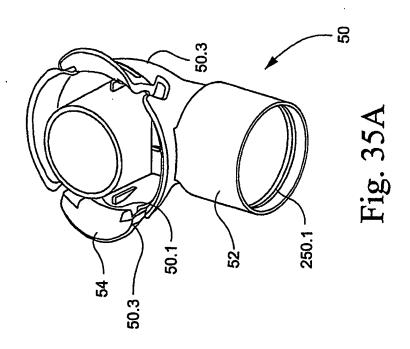




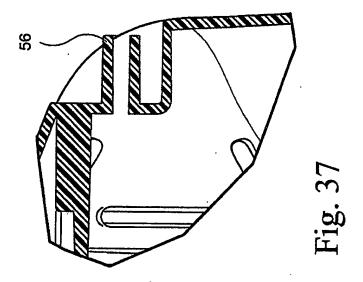


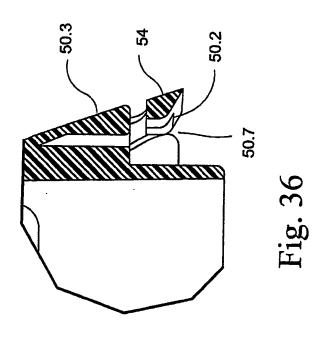
SUBSTITUTE SHEET (RULE 26)



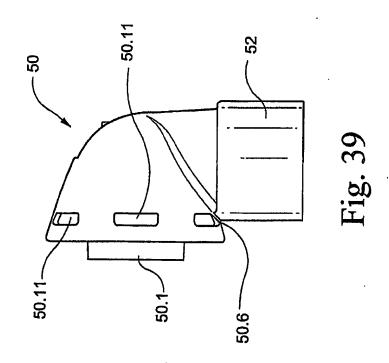


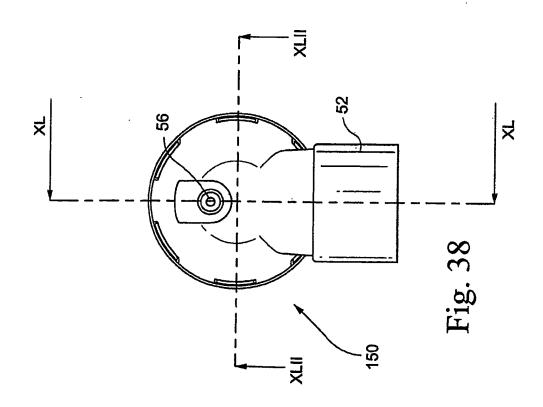
SUBSTITUTE SHEET (RULE 26)



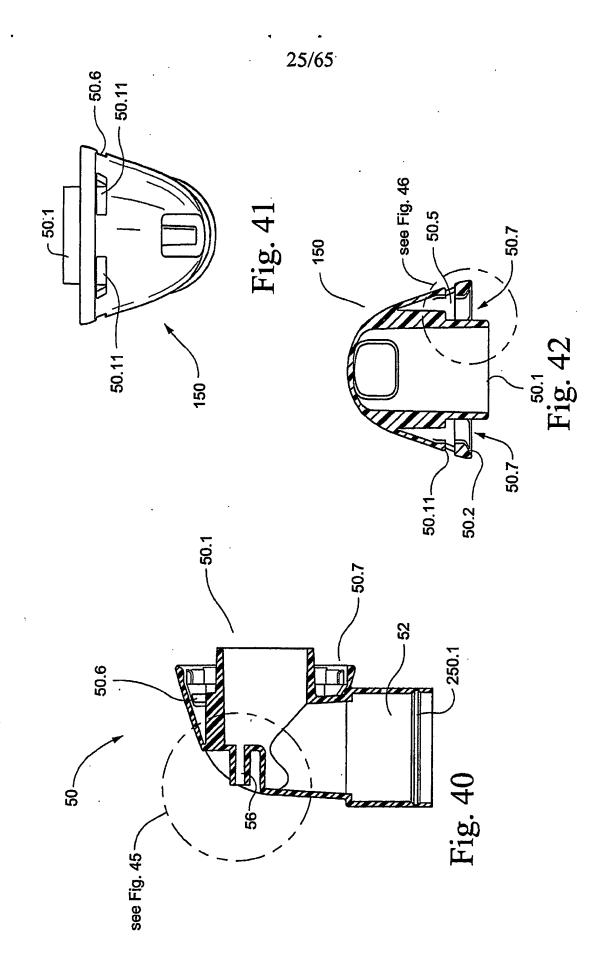


SUBSTITUTE SHEET (RULE 26)

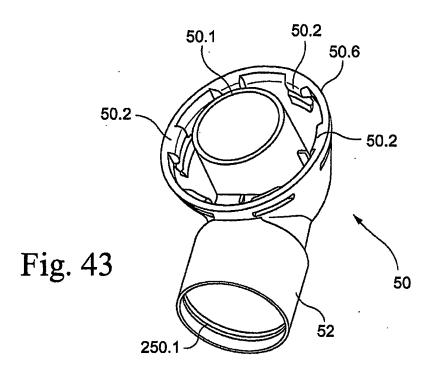




SUBSTITUTE SHEET (RULE 26)



. 26/65



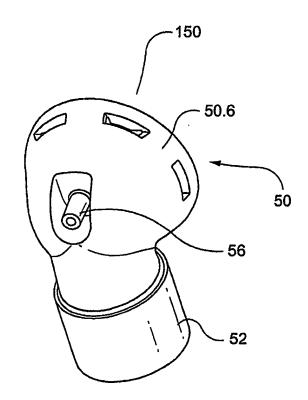


Fig. 44

27/65

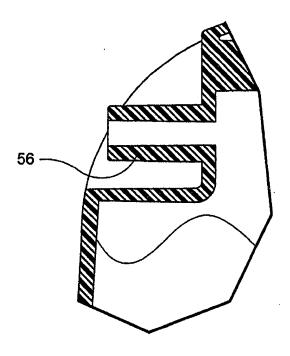


Fig. 45

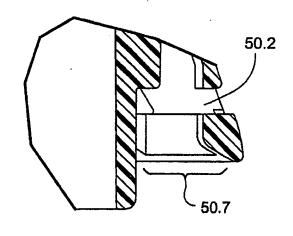
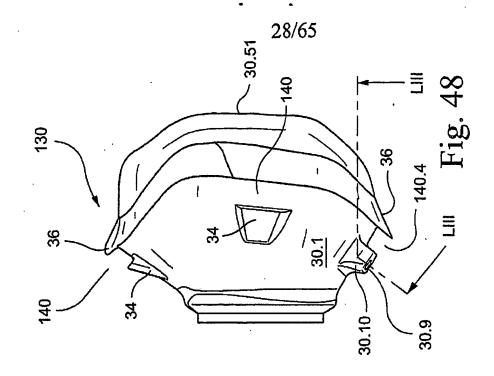
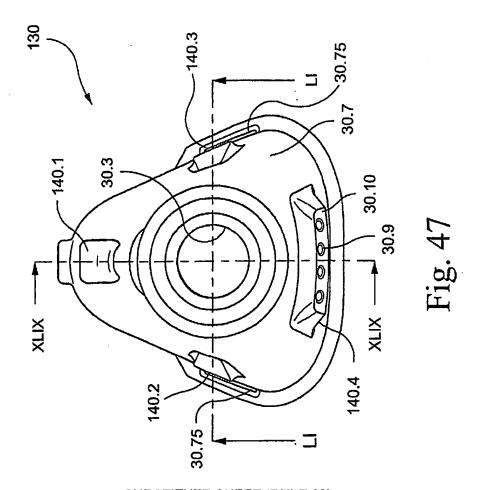


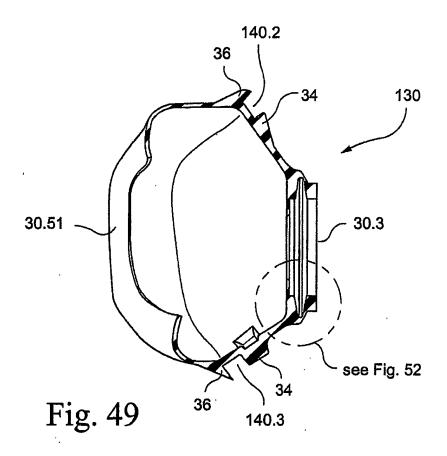
Fig. 46





SUBSTITUTE SHEET (RULE 26)

. 29/65



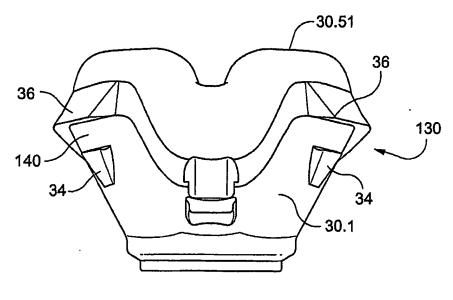
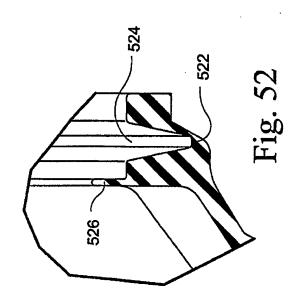
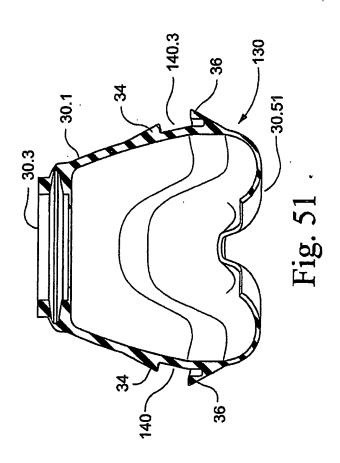
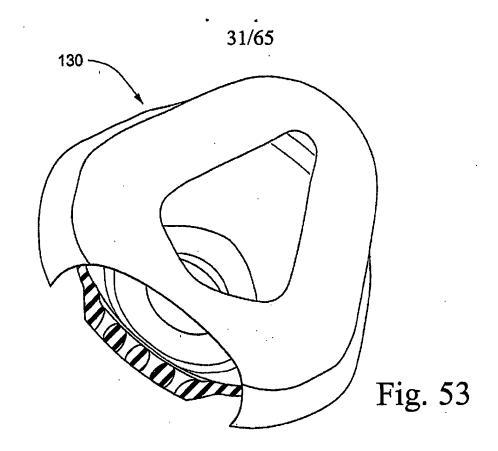


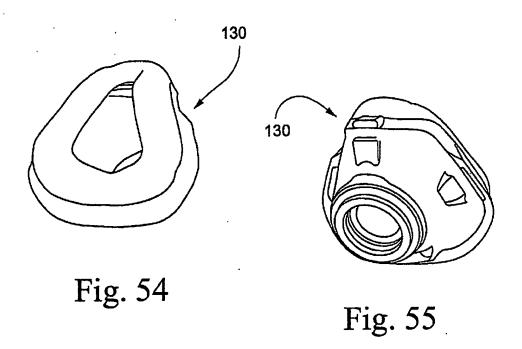
Fig. 50





SUBSTITUTE SHEET (RULE 26)





32/65

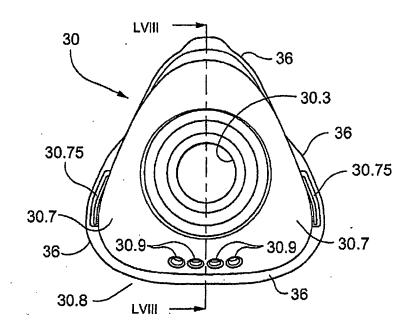
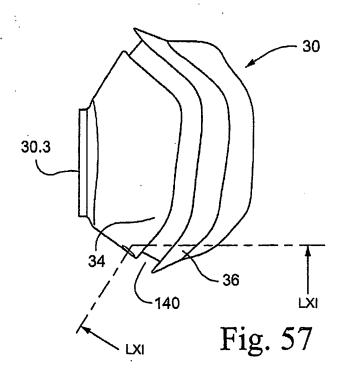
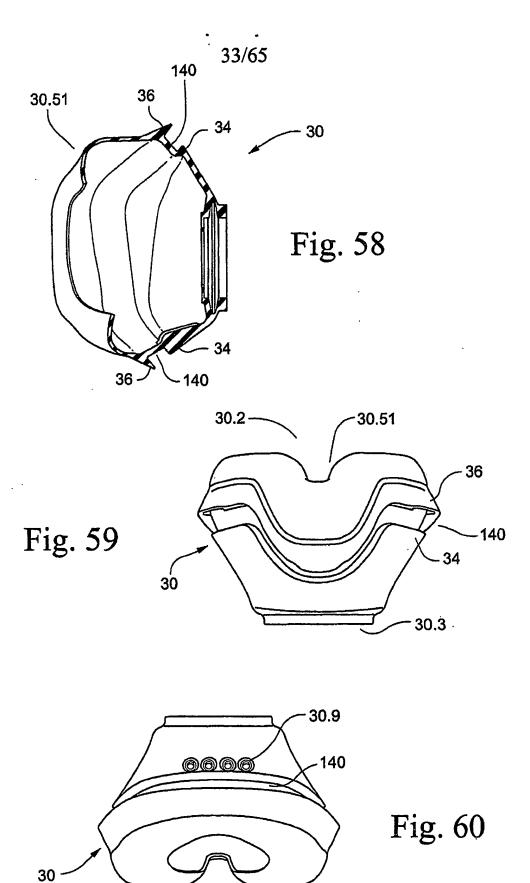


Fig. 56

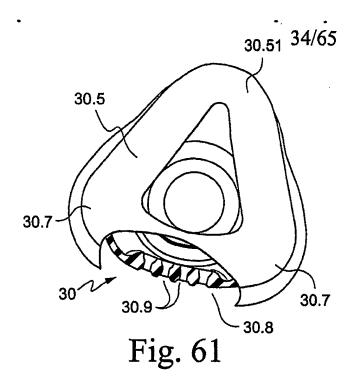


SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)

-30.51



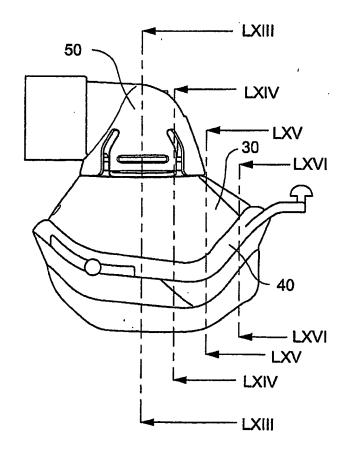
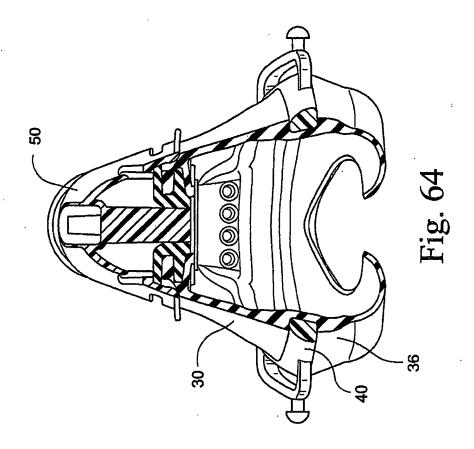
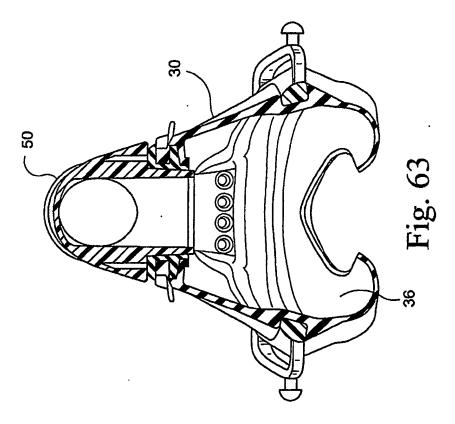
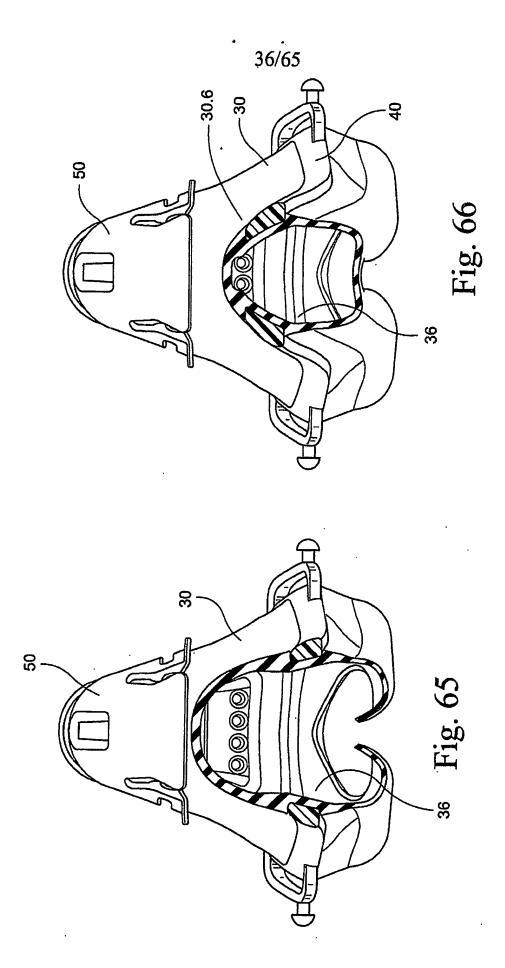


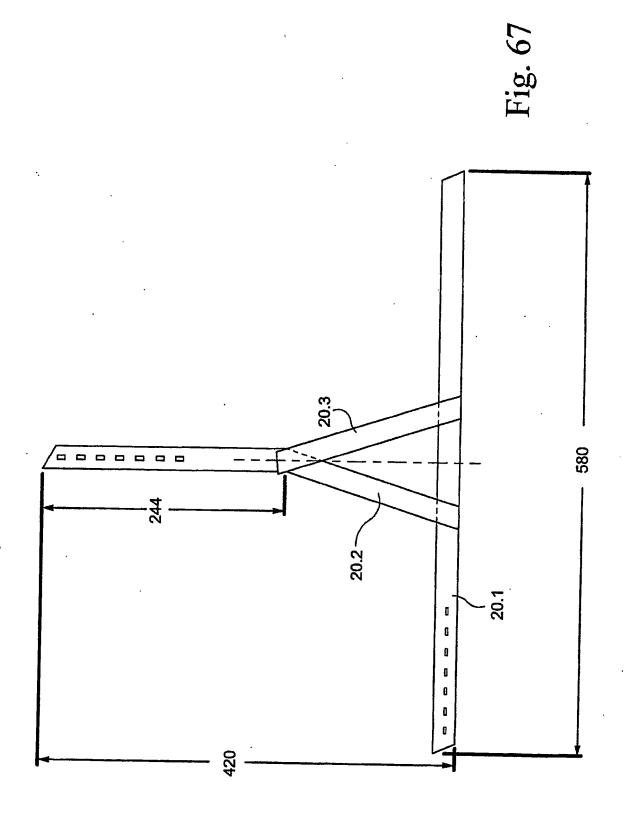
Fig. 62





SUBSTITUTE SHEET (RULE 26)





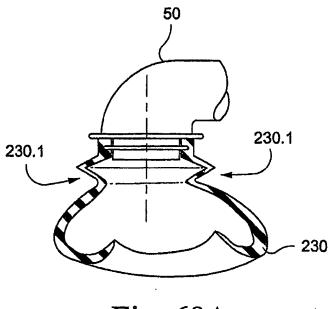


Fig. 68A

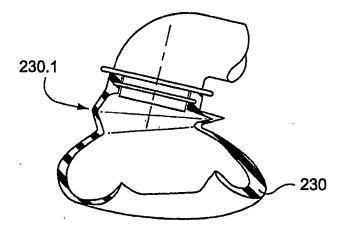
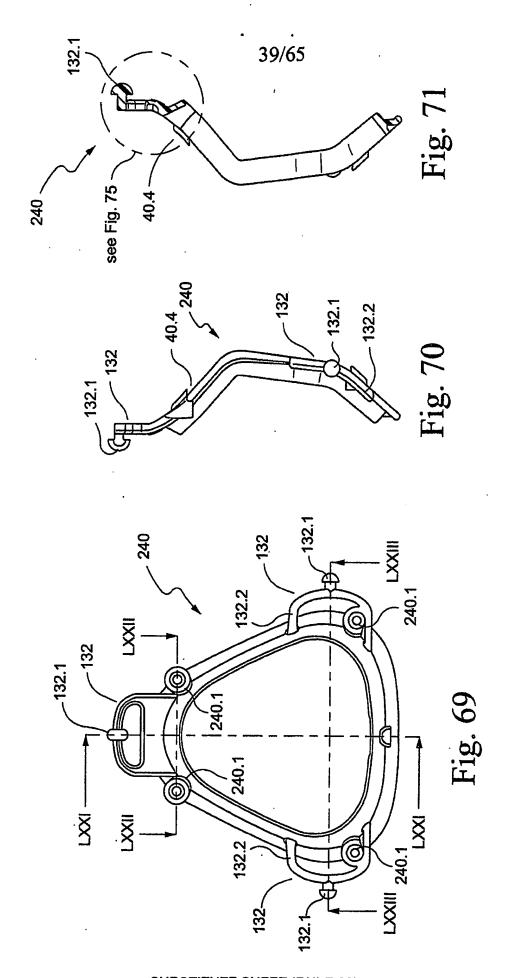
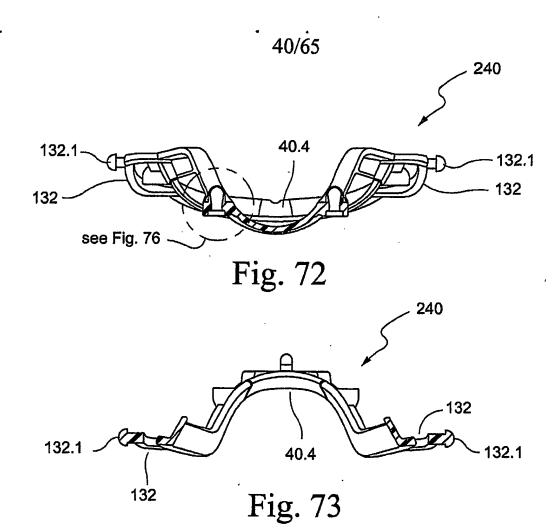


Fig. 68B



SUBSTITUTE SHEET (RULE 26)



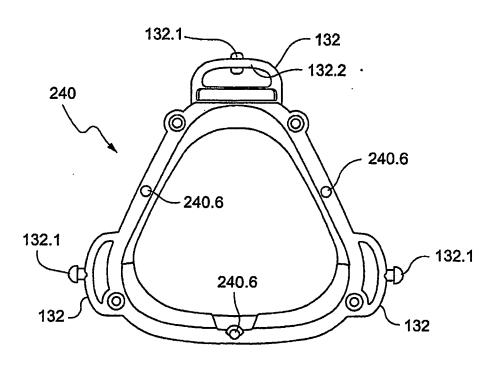
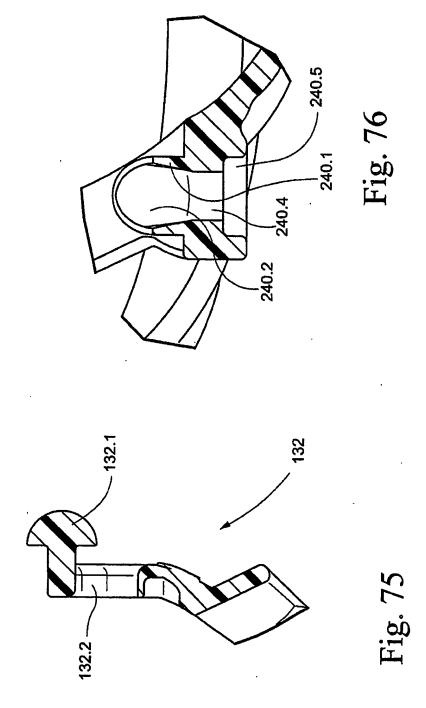
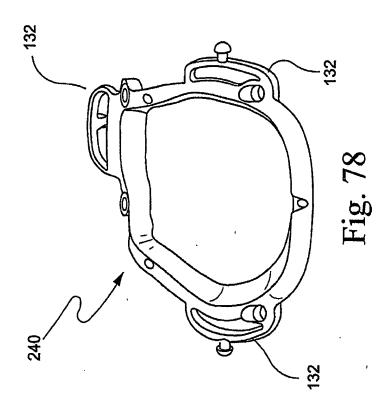
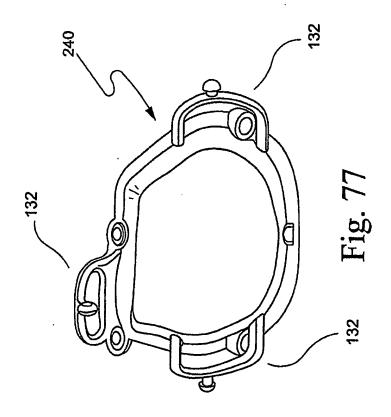


Fig. 74

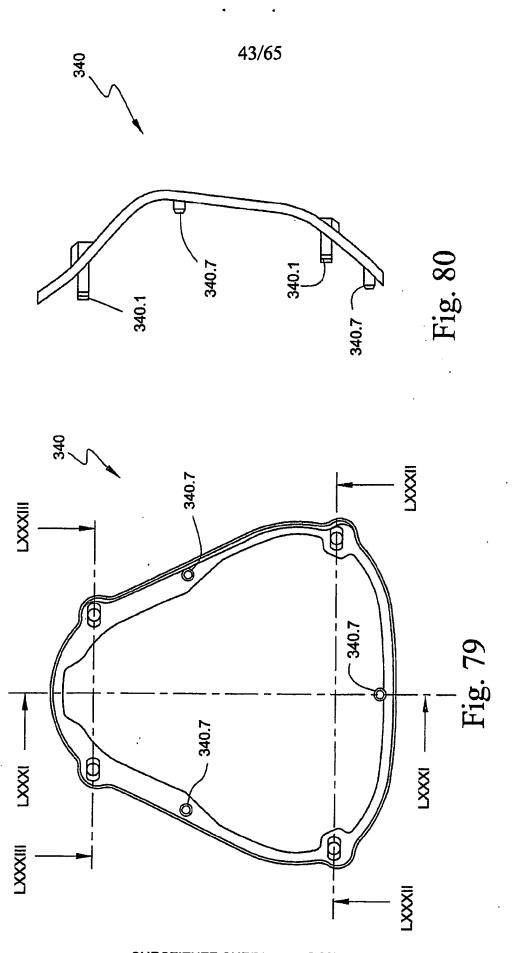
41/65





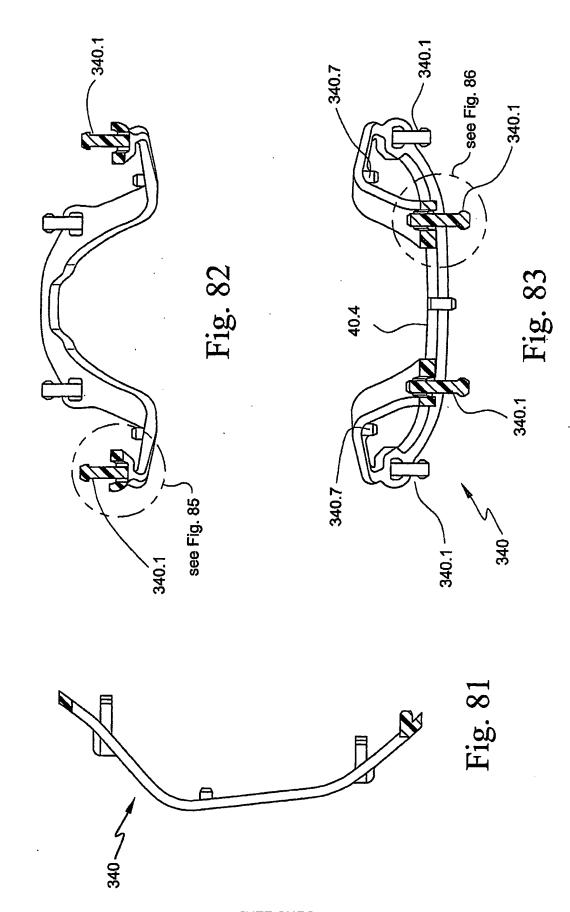


SUBSTITUTE SHEET (RULE 26)

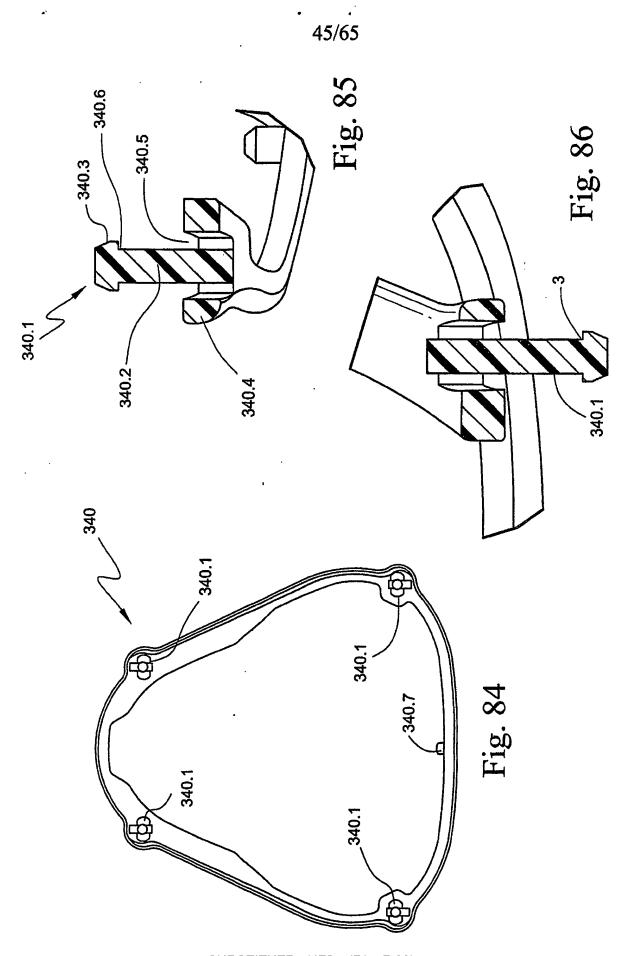


SUBSTITUTE SHEET (RULE 26)

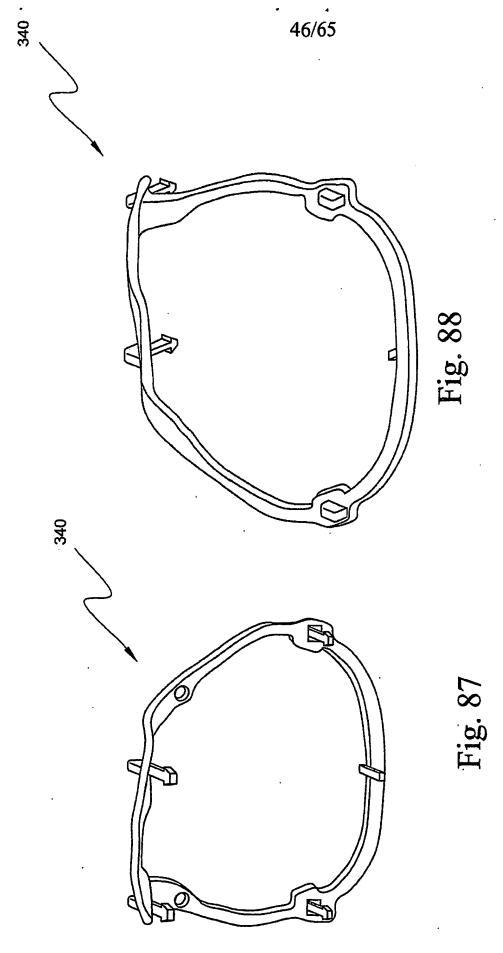
44/65



SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)

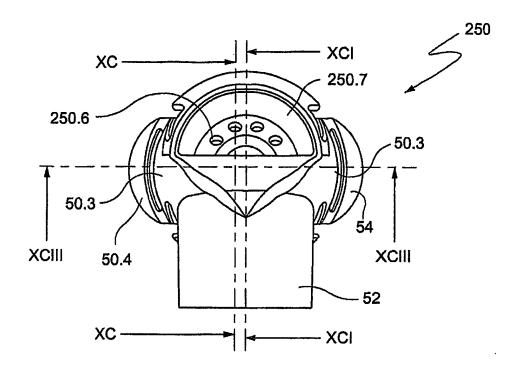


Fig. 89

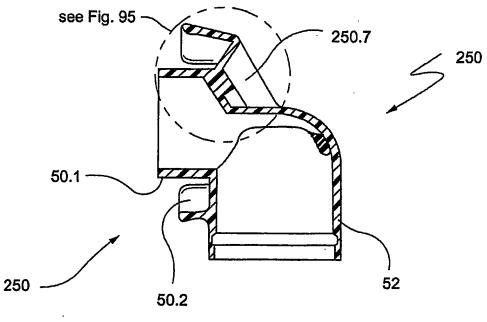
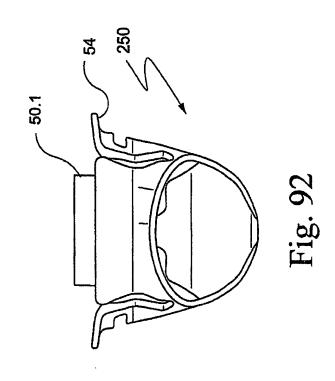
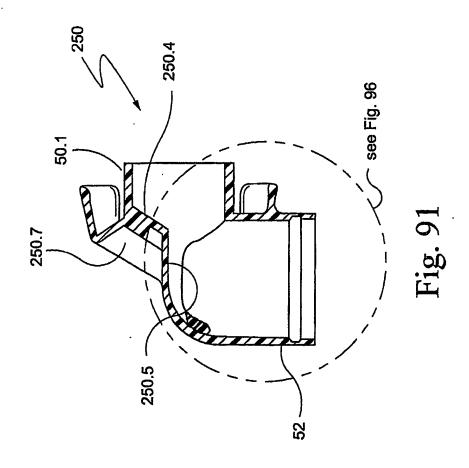


Fig. 90





SUBSTITUTE SHEET (RULE 26)



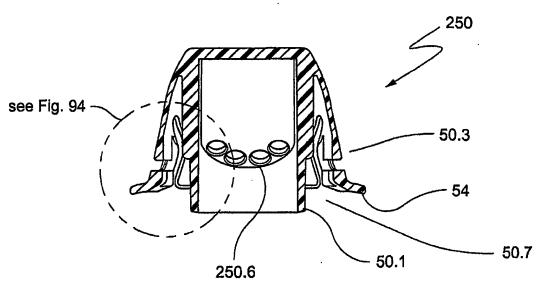
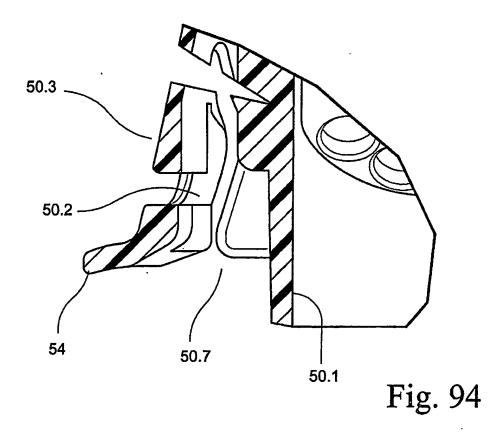
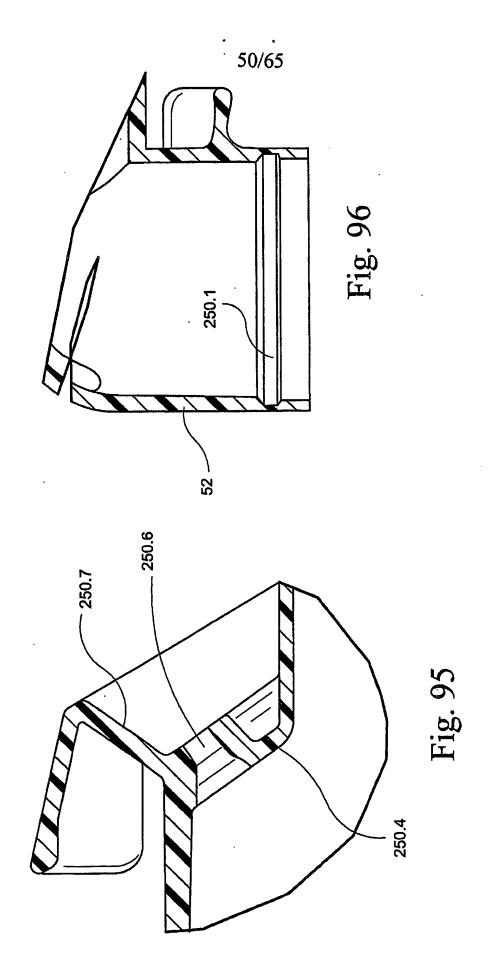


Fig. 93





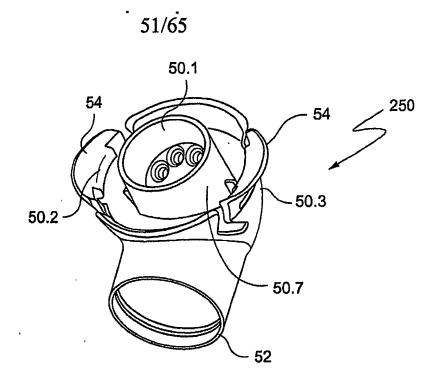


Fig. 97

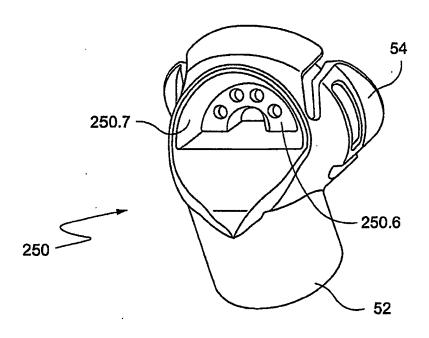


Fig. 98

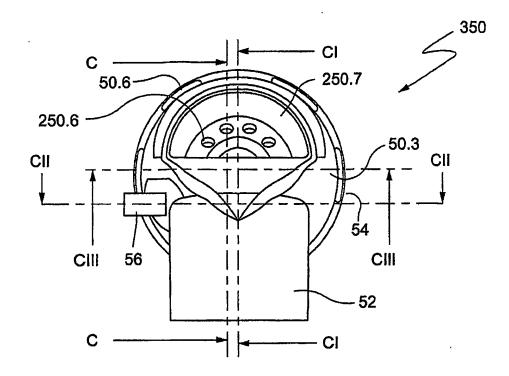


Fig. 99

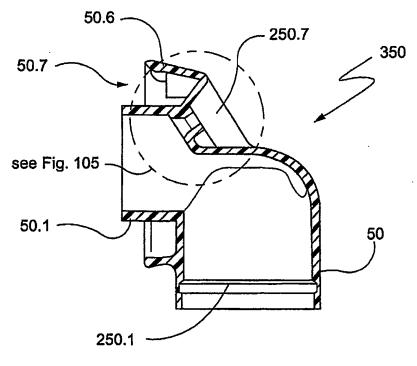
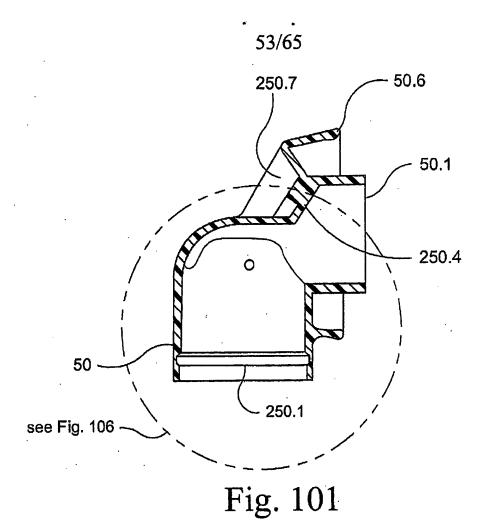


Fig. 100



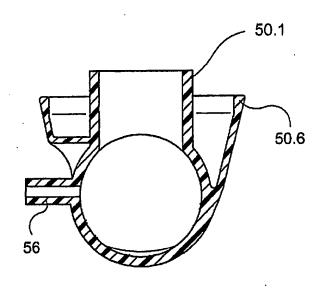
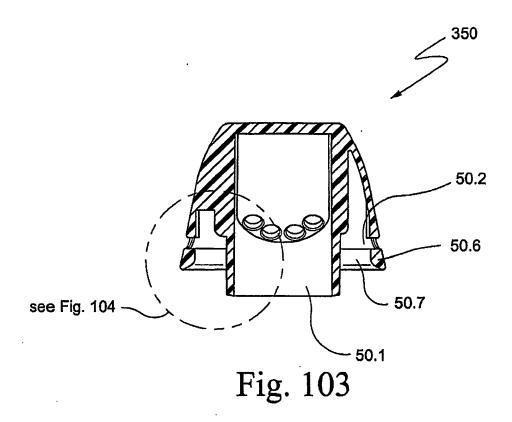
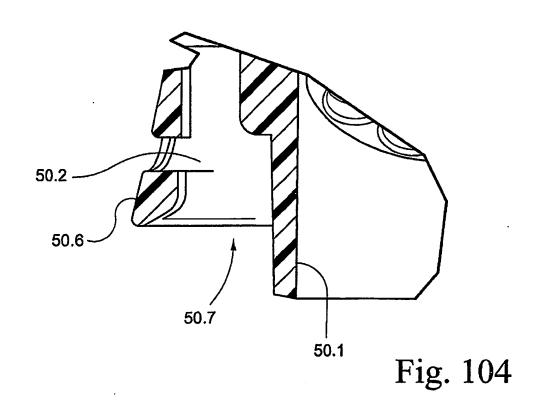
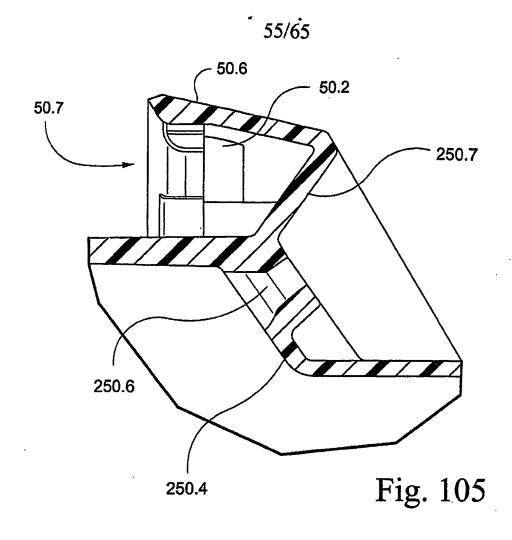
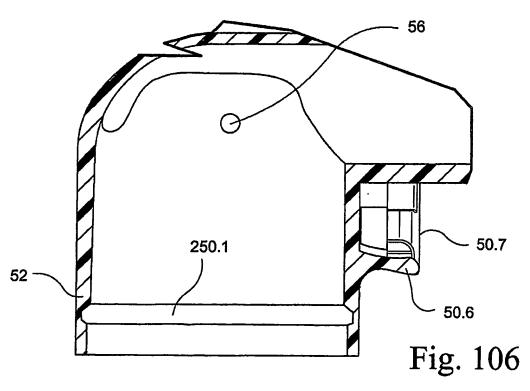


Fig. 102









SUBSTITUTE SHEET (RULE 26)

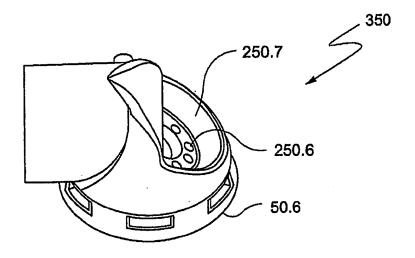
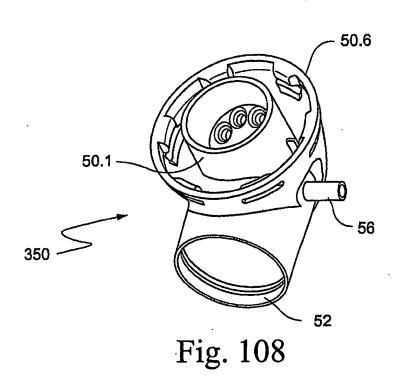
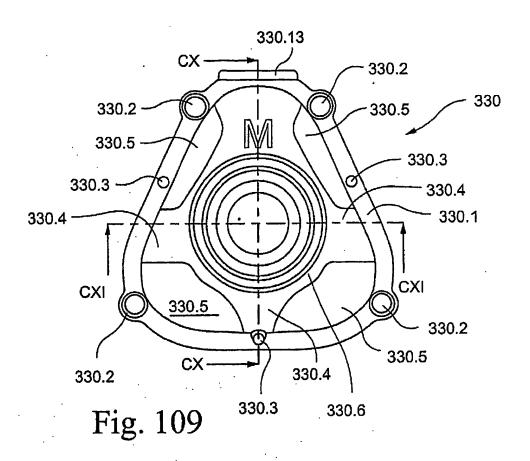


Fig. 107







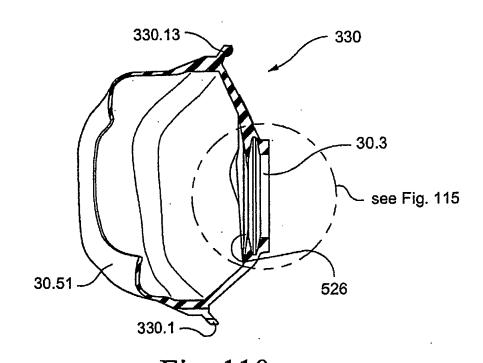


Fig. 110

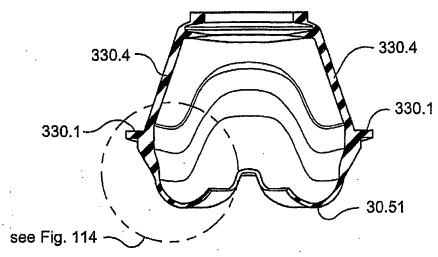
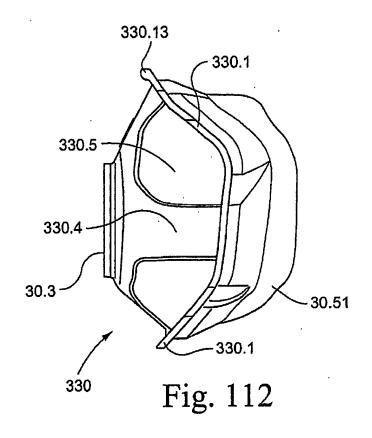
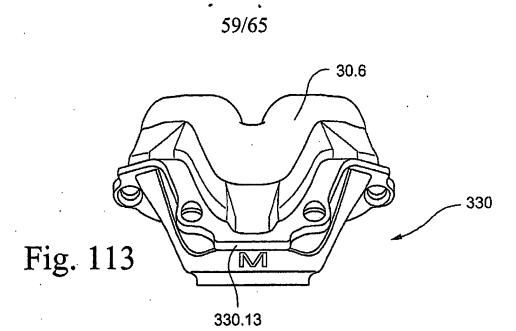
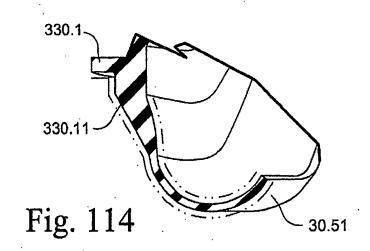
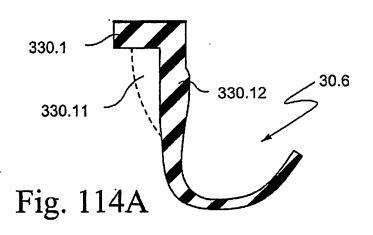


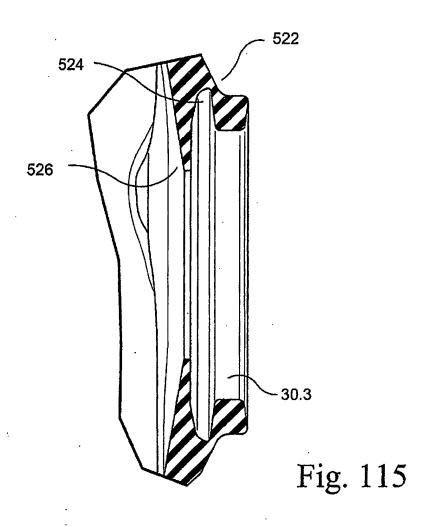
Fig. 111

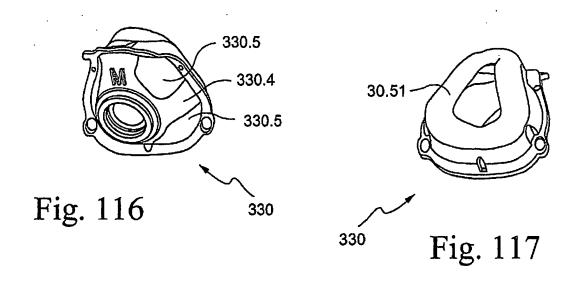


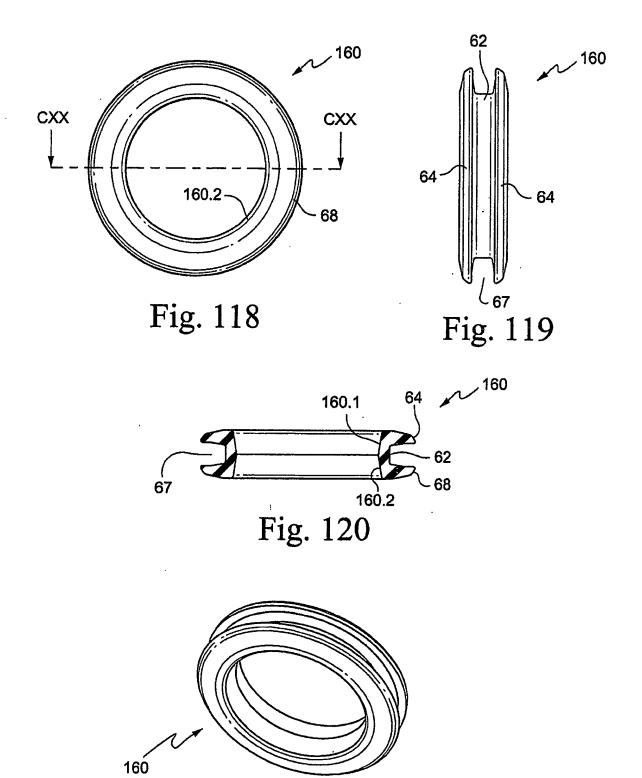






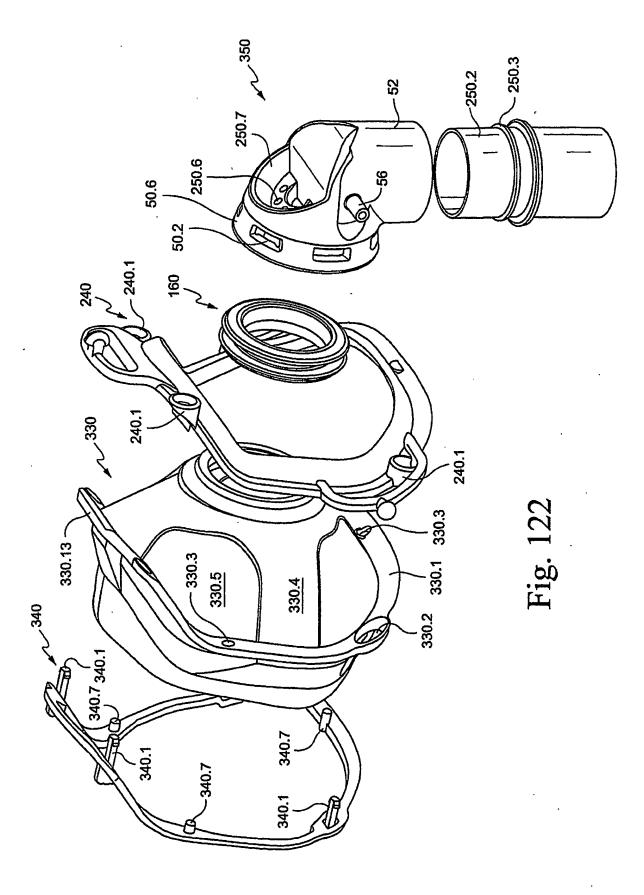




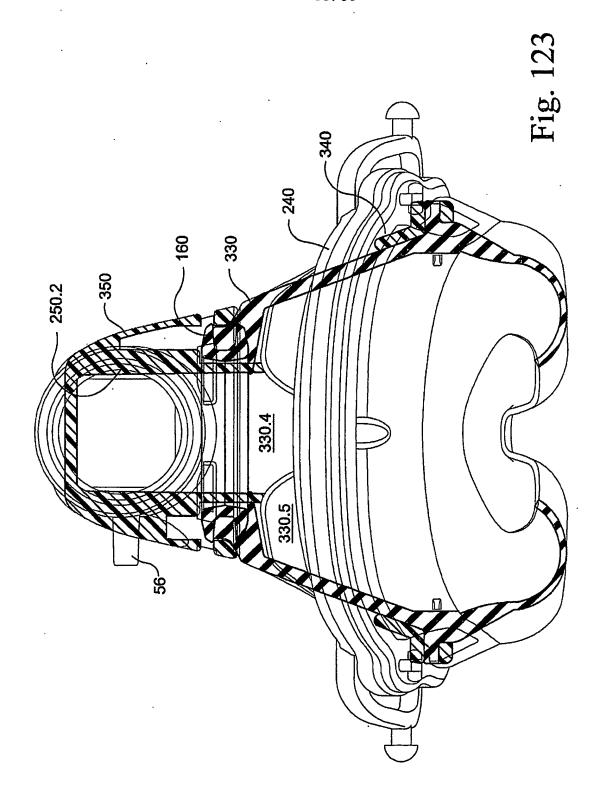


SUBSTITUTE SHEET (RULE 26)

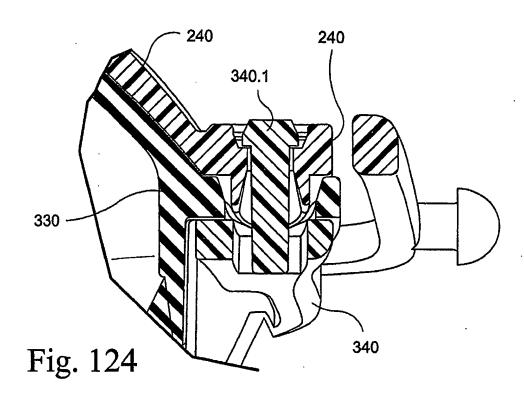
Fig. 121

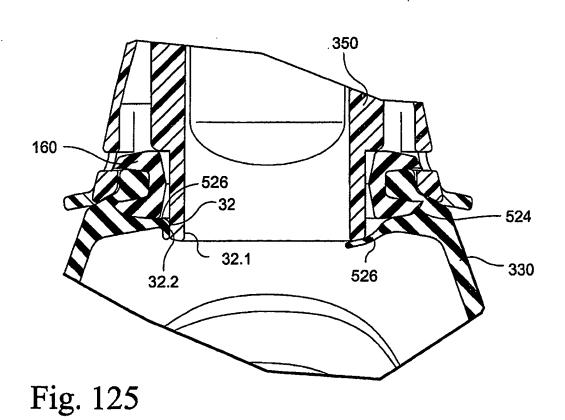


SUBSTITUTE SHEET (RULE 26)









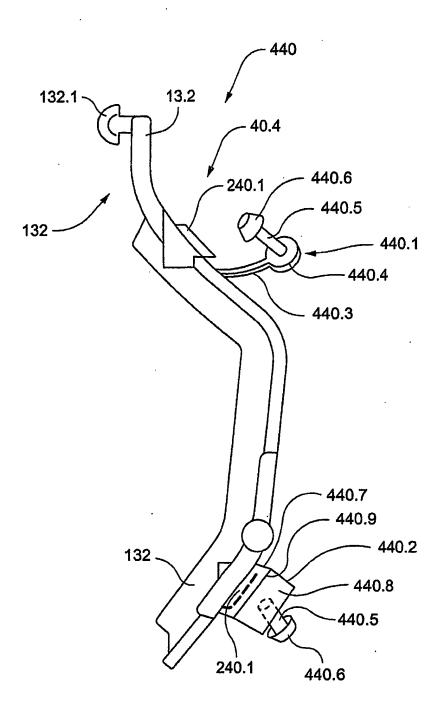


Fig. 126

International application No. PCT/AU2004/000563

| Α. | CLASSIFICATION OF SUBJECT MATTER | | | | |
|----------------------------------|--|--|---|--|--|
| Int. Cl. 7: | A61M 16/06 | | | | |
| According to | International Patent Classification (IPC) or to both na | tional classification and IPC | | | |
| В. | FIELDS SEARCHED | • | | | |
| Minimum docu | mentation searched (classification system followed by class | sification symbols) | | | |
| Documentation | searched other than minimum documentation to the extent | that such documents are included in the fields search | ned | | |
| DWPI - IPC | base consulted during the international search (name of da A61M, A62B & Keywords (mask, interfac, retaion, pad) and like terms | ta base and, where practicable, search terms used) in, secur, ring, clip,, elbow, bend, flange, be | order, channel, | | |
| C. | DOCUMENTS CONSIDERED TO BE RELEVANT | | | | |
| Category* | Citation of document, with indication, where appro | priate, of the relevant passages | Relevant to claim No. | | |
| A | EP 1057494 A2 (SLEEPNET CORP) 6 Decer Whole document | mber 2000 | | | |
| A | EP 1027905 A2 (RESMED LTD) 16 August 2 Whole document | 2000 | | | |
| A | WO 200245784 A1 (RESMED LTD) 13 June Whole document | 2002 | | | |
| A | WO 200021600 A1 (TAEMA) 20 April 2000 Whole document | | | | |
| X F | Further documents are listed in the continuation | of Box C X See patent family arm | ex | | |
| "A" docume not con: | not considered to be of particular relevance conflict with the application but cited to understand the principle or theory underlying the invention document of particular relevance; the claimed invention cannot be considered novel | | | | |
| "L" docume or whic another | alor which may throw doubts on priority claim(s) h is cited to establish the publication date of citation or other special reason (as specified) such targeting to an oral disclosure, use, exhibition | ne sument of particular relevance; the claimed invention cannot olve an inventive step when the document is combined with h documents, such combination being obvious to a person s | t be considered to one or more other | | |
| or other | reans reans reans reans reans the published prior to the international filing date r than the priority date claimed | rument member of the same patent family | | | |
| Date of the act | tual completion of the international search | Date of mailing of the international search report | 2 3 JUL 2004 | | |
| 31 May 200 | | · | | | |
| | ling address of the ISA/AU | Authorized officer | | | |
| PO BOX 200, | N PATENT OFFICE WODEN ACT 2606, AUSTRALIA s: pet@ipaustralia.gov.au | Sue Thomas | | | |
| | (02) 6285 3929 | Telephone No : (02) 6283 2454 | | | |

International application No.
PCT/AU2004/000563

| C (Continuati | on). DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|---------------|--|-----------------------|--|
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. | |
| A | US 6467483 B1 (KOPACKO et al)) 22 October 2002 Whole document | | |
| | | | |
| | · | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | ļ | |
| | | | |
| | | | |
| | | | |
| | · | | |
| | | | |
| | | • | |
| | · | | |
| | | | |
| | | | |
| | · | | |
| | | | |
| | | | |

International application No.

| This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons: 1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely: |
|---|
| |
| because they relate to subject matter not required to be searched by this Authority, namely: |
| |
| |
| · |
| • |
| |
| 2. Claims Nos.: |
| because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically: |
| |
| |
| |
| 3. Claims Nos.: |
| because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a) |
| |
| Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet) |
| This International Searching Authority found multiple inventions in this international application, as follows: |
| Claims 1, 2, 50, and 51 are directed to a mask system comprising headgear, a shell/oushion including a channel adjacent a front aperture, a frame, an elbow including at least one undercut on a proximal end having the first special technical feature of a retaining ring including a rear flange adapted to be retainably insertable in the channel of the shell/cushion and a front flange adaptable to retainably engage with the at least one undercut of the elbow. Continued in supplemental box |
| 1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims. |
| 2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee. |
| 3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.: |
| |
| |
| |
| 4. X No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:1, 2, 50, 51 |
| |
| Remark on Protest |
| No protest accompanied the payment of additional search fees. |

International application No.

PCT/AU2004/000563

| Supplemental Box | Sui | ga | lem | enta | B | co |
|------------------|-----|----|-----|------|---|----|
|------------------|-----|----|-----|------|---|----|

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

Claims 3 to 5 are directed to a mask system headgear, a frame, and shell/cushion including a frame receiving channel defined by a front flange and a rear flange the front flange extending 75%-100% of the way around the perimeter of the shell/cushion having the second special technical feature that the frame is adapted to be removably insertable in the frame - receiving channel of the shell/cushion.

Claims 6-28 are directed to a connection piece for connecting a mask to a conduit.

Claims 29-47 are directed to a mask or mask system, the mask having a shell/cushion with an inner and outer surface, a flange extending away from said outer surface and surrounding said shell/cushion, said mask having an exoskeletal frame which substantially matches the contours of said flange so that said frame can be positioned adjacent said flange when said shell/cushion is in a shape suitable for use by a patient and structure or means to hold said flange to said frame.

Claims 48, 49,52 and 53 are directed to a mask system and include the connection piece of any one of claims 6 to 28 in their scope.

Information on patent family members

International application No.

PCT/AU2004/000563

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| | t Document Cited in Search Report | | | Pate | nt Family Member | | |
|----|--------------------------------------|----|------------|------|------------------|----|------------|
| EP | 1057494 | AU | 51653/00 | CA | 2310919 | CA | 2375928 |
| | | EP | 1189650 | US | 6631718 . | wo | 0074758 |
| EP | 1027905 | AU | 12454/97 | AU | 14892/00 | AU | 16355/00 |
| | | AU | 16811/02 | AU | 26505/00 | AU | 34293/97 |
| | | AU | 42476/99 | AU | 49012/00 | AU | 52005/00 |
| | • | AU | 52007/00 | AU | 52691/00 | AU | 61522/01 |
| | | CA | 2261790 | CA | 2298129 | EP | 0956069 |
| | | EP | 1187647 | EP | 1187648 | EP | 1187649 |
| | | EP | 1187650 | лР , | 2000279520 | JР | 2004041779 |
| | | NZ | 513052 | NZ | 526165 | US | 6112746 |
| | | US | 6357441 | US | 6374826 | US | 6412487 |
| | | US | 6428231 | US | 6439230 | US | 6491034 |
| | • | US | 6532961 | US | 6561710 | US | 6585441 |
| | | US | 6691707 | US | 2002005198 | US | 2002005200 |
| | | US | 2002023649 | US | 2002023650 | US | 2002029781 |
| | | US | 2002074001 | US. | 2002083948 | US | 2002096176 |
| | | US | 2002104540 | US | 2002108613 | US | 2002153012 |
| | • | US | 2002157672 | US | 2002174867 | US | 2002174868 |
| | | US | 2003034034 | US | 2004025881 | US | 2004086319 |
| | | US | 2004094159 | US | 2004099272 | WO | 0078381 |
| | | WO | 0078382 | WO | 0078383 | wo | 0078384 |
| | | WO | 0134406 | WO | 0184979 | WO | 9804310 |
| wo | 0245784 | AU | 20362/02 | EP | 1345644 | US | 2004065328 |
| wo | 0021600 | AU | 60950/99 | EP | 1121172 | FR | 2784298 |
| US | 6467483 | US | 2003019496 | | | | |

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX